



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUN 18 1999

4100 '99 JUN 21 A9:53

Ira L. Goldberg
President
Source Naturals
19 Janis Way
Scotts Valley, California 95066

Dear Mr. Goldberg:

This is in response to your letter of May 25, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Source Naturals is making the following claims for the product Bone Renew:

"Lack of adequate dietary calcium can cause a loss of bone strength and thinning of bones, something of particular concern to women in their menopausal years"
"Clinical studies on post-menopausal women have shown that ipriflavone, a naturally occurring isoflavone, helps to maintain bone mineral density when combined with calcium"
"Minimizes bone loss"

These statements are not claims subject to 21 U.S.C. 343(r)(6), but claims subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis. The product Bone Renew, which is mentioned in the claim, may be eligible for the health claim in 21 CFR 101.72 on the basis that it contains adequate calcium to qualify for the claim. However, FDA has not authorized a health claim for the relationship between ipriflavone or other isoflavones and osteoporosis. Therefore, specific claims that ipriflavone or isoflavones help to maintain bone density is an unauthorized health claim and it misbrands the dietary supplement under 21 U.S.C. 343(r)(1)(B).

975-0163

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Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

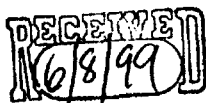
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file)
HFS-450 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605 (Bowers)
HFV-228 (Benz)
GCF-1 (Dorsey, Barnett)
f/t:HFS-456:rjm:6/16/99:docname:65510.adv:disc38

SOURCE

NATURALS

May 25, 1999

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. S.W.,
Washington, D.C. 20204



RE: Notification of Nutritional Support Statements

Dear Sir or Madam:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of Bone Renew, a dietary supplement. Source Naturals® is the manufacturer of Bone Renew.

Statements being made in the labeling of Bone Renew:

- (1) Lack of adequate dietary calcium can cause a loss of bone strength and thinning of bones, something of particular concern to women in their menopausal years.
- (2) Clinical studies on post-menopausal women have shown that ipriflavone, a naturally occurring isoflavone, helps to maintain bone mineral density when combined with calcium.
- (3) Minimizes bone loss.

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. Source Naturals possesses substantiation that the statements are truthful and not misleading.

Ira L. Goldberg
President, Source Naturals®

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